Informed Consent Form

A Phase II Multi-institutional Study of Concurrent Radiotherapy, Palbociclib, and Hormone Therapy for Treatment of Bone Metastasis in Breast Cancer Patients

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You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

EMORY | WINSHIP CANCER INSTITUTE
A Cancer Center Designated by the National Cancer Institute

Emory University, Grady Health System, and Saint Joseph's Hospital
Consent to be a Research Subject / HIPAA Authorization

Title: A Phase II Multi-institutional Study of Concurrent Radiotherapy, Palbociclib, and Hormone Therapy for Treatment of Bone Metastasis in Breast Cancer Patients

Principal Investigator: Mylin A. Torres, MD

Study-Supporter: Pfizer Oncology

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

Why am I being asked to participate in this research?
You are being asked to participate in a research study because you have hormone receptor positive (HR+)/human epidermal growth factor receptor 2 negative (HER2-) metastatic breast cancer that has spread to your bones and you are currently taking palbociclib (i.e. ibrance) and hormone therapy (e.g. exemestane, arimidex, tamoxifen, fulvestrant, or letrozole) to treat it. A member of the research team will explain what is involved in this study and how it will affect you. This consent form describes the study procedures, the risks and benefits of participation, as well as how your confidentiality will be maintained. Please take your time to ask questions and feel comfortable making a decision whether to participate or not. This process is called informed consent. If you decide to participate in this study, you will be asked to sign this form.

What is the purpose of this study?
The purpose of this study is to is to evaluate how safe and effective radiation treatment is in treating breast cancer that has spread to the bones while a patient is receiving palbociclib (i.e. ibrance) and hormone therapy (e.g. exemestane, arimidex, tamoxifen, fulvestrant, or letrozole) at the same time. This

research study is a Phase II clinical trial, which tests the safety and effectiveness of an investigational combination of radiation, palbociclib, and hormone therapy for metastatic breast cancer that has spread to the bone.

Radiation is a routine, medical treatment which improves pain, weakness, feelings of numbness, and/or prevents bones from breaking in patients who have breast cancer that has spread to the bones. Palbociclib has been approved by the FDA to be used in combination with an aromatase inhibitor, a form of anti-hormone therapy, to treat metastatic, HR+/HER2- breast cancer, which is cancer that has spread from the primary site (breast) to other parts of the body (distant sites). Palbociclib is a drug that may stop cancer cells from growing. Palbociclib blocks activity of two closely related enzymes (proteins that help chemical reactions occur in the body), called Cyclin D Kinases 4 and 6 (CDK 4/6). These proteins are part of a pathway, or a sequence of steps, which is known to regulate cell growth. Laboratory testing has suggested Palbociclib may stop the growth of HR+ breast cancer.

Anti-hormone therapy prevents breast cancer cell growth by blocking estrogen receptor stimulation. During this study, anti-hormone therapy will consist of either tamoxifen, faslodex, or aromatase inhibitor (anastrozole, letrozole, exemestane). Premenopausal women may also receive an injection drug called an LHRH (luteinizing hormone-releasing hormone) agonist to shut down ovary function. Standard care for people with HR+ breast cancer is anti-hormone therapy. Your study doctor will determine which standard anti-hormone therapy you will receive during this research study, and you will continue taking palbociclib and anti-hormone therapy during radiation treatment for your bone metastasis.

The purpose of this study is to determine any good and bad effects of 5 to 10 days of standard radiation treatment to the bone in metastatic breast cancer patients who are also taking standard palbociclib and hormone therapy.

We anticipate enrolling 42 subjects onto the study at Emory and elsewhere.

What will I be asked to do?

Radiation is often routinely prescribed to improve pain, weakness, feelings of numbness, and/or prevent bones from breaking in patients who have breast cancer that has spread to the bones. Palbociclib (i.e. ibrance) and hormone therapy (e.g. exemestane, arimidex, tamoxifen, fulvestrant, or letrozole) given together is the standard treatment for metastatic breast cancer patients that have cancer which is hormone receptor positive (e.g. estrogen and/or progesterone receptor positive) and Her2 negative. If you have hormone receptor positive breast cancer that has spread to the bone and you have been taking palbociclib and hormone therapy for at least 28 days, you will be asked to continue taking palbociclib (i.e. ibrance) and hormone therapy (e.g. exemestane, arimidex, tamoxifen, fulvestrant, or letrozole) during the 5 or 10 days of radiation treatment prescribed to the boney areas where the breast cancer is causing you symptoms or is weakening the bone.

Your doctor will prescribe 5 or 10 days of radiation treatment to site of boney disease. If you receive 5 days of radiation, you will be seen within 2 weeks prior to radiation (baseline visit) and the last day of radiation (day 5). If you receive 10 days of radiation, you will be seen within 2 weeks prior to radiation (baseline visit) the last day of radiation (day 10). All enrolled patients will then be seen at two additional follow up assessments: 3-7 weeks post last day of radiation and 11 to 16 weeks after the last day of radiation treatment. There are a total of 4 study visits corresponding to your usual visits with physicians who would see you at these time points whether you do or do not participate on this study.

At each time point, you will be asked to fill out questionnaires about your symptoms, including pain, fatigue, quality of life, and mood. These will include: a demographic datasheet, a pain survey (Brief Pain Inventory), an anxiety and depression survey (HADS), a health and quality of life survey (SF-36), and a fatigue survey (MFI).

These questionnaires take about 20 to 30 minutes in total to complete. Additionally, medical records will be accessed and a pregnancy test may occur if patients are of child bearing potential.

So that side effects can be assessed, blood tests to monitor your red, white, and platelet blood counts along with blood chemistries such as potassium, liver function tests will be done before and after radiation treatment at 3-7 weeks after the last day of radiation, and again, at 11 to 16 weeks after your last day of radiation treatment. A blood test to monitor your red, white, and platelet blood counts will also be done on your last day of radiation. These tests will be charged to you and your insurance as normal care. This will allow your physician to monitor your blood counts and provide you with additional support if needed.

Before the first radiation treatment and 11 to 16 weeks after the last radiation treatment, you will also be asked to give a small sample of blood (up to 35 mL, or about 2 tablespoons), collected from a vein in your arm or port by a healthcare professional. We will use this blood to determine if there are substances within your blood which help us to better understand metastatic breast cancer or side effects from treatment. To prepare for these blood draws which will occur first thing in the morning, you will be asked not to eat or drink anything but water and your medications after midnight. After the blood draw, you will be able to eat and drink as normal. The entire procedure should take approximately 5 minutes or less.

How long will I be in this study?
Participants of this trial will be monitored up to 16 weeks after radiation treatment completion.

What tests and procedures will I have if I take part in this study?
Most of the exams, tests, and procedures you will have are part of the usual approach for the care of your cancer. However, there are some extra exams that you will need to have if you take part in this study.

Screening Procedures
You will need to have the following exams to find out if you can continue in the study:
• Demographic information about you will be collected (age, sex, race/ethnicity)
• Your medical history will be examined.
• Full Physical Exam with vital signs (height, weight, blood pressure and pulse).
• You will be asked about medications you are taking.
• The study doctor will evaluate your performance status (how well you can carry out daily activities)
• Blood or urine pregnancy test (if you are premenopausal, able to have children). The study doctor or study staff will tell you if the pregnancy test results are positive. The results of the pregnancy testing must be negative in order for you to be in the study.
• Blood tests to evaluate your red, white, and platelet blood counts along with blood chemistries such as potassium, liver function tests, etc.
• Blood draw for study specific research lab assessment, described in further detail above.

During the main part of the study:
If you continue in the study after screening, you will have to come to the study site prior to starting radiation, during radiation, and after you stop taking radiation treatment (but still taking your anti-hormone therapy and palbociclib). During your participation on the study, there will be four total visits to the study site.

The following procedures will be performed. To find out which procedures occur at which visit, please ask the study doctor or study staff:

• Medical history – your study doctor will ask you questions about your health, general condition, complaints, and medications that you are taking or have taken prior to randomization (the day you are assigned to a study arm). It is important that you tell your study doctor about all the medications that you have been taking, including any medications or herbal remedies that you may have bought for yourself.

• Tumor Assessments (e.g. Chest X-ray, Computerized Tomography (CT) Scan, PET/CT, MRI or Bone Scan): The study doctor or study staff will collect the results from scans you have as part of your regular care to help assess your tumor.
• Physical examination – your study doctor will periodically examine your body, including measuring your height and weight, your blood pressure, and pulse rate.
• A check of your performance status (your ability to carry out daily activities) will also be performed.
• Blood tests – to allow monitoring of the body's function and its response and reaction to study drug and breast cancer, up to 35 ml blood will be taken at screening and at each of your study visits until end of dosing. This will help determine how you are tolerating treatment. Your blood may also be tested to see if you are pregnant and if your ovaries are still actively producing sex hormones. There is also a test for tumor DNA circulating in your blood.
• Questionnaires – You will be asked to fill out 4 forms assessing pain, quality of life, fatigue, anxiety, and depression, described above. Each form will take about 5-10 minutes to complete. The forms will ask about things like fatigue and sexual function. You may feel uncomfortable answering some of the questions, and you can skip any you do not want to answer. Completing all of the forms will take about 20-30 minutes.

While you are in the study, you must:
• Follow instructions you are given.
• Come to the study center for all visits with the study doctor or study staff.
• Tell the study doctor or study staff about any changes in your health or the way you feel.
• Tell the study doctor or study staff if you want to stop being in the study at any time.

Will I need time to recover after my participation in the study?
Ask the study doctor or study staff for the estimated recovery time of your participation in this study.

How will my medicine be provided?
The palbociclib and hormone therapy you take are part of the usual approach for the care of your cancer. These medications will be prescribed to you by your treating physician and dispensed by the pharmacy directly to you. Because these treatments are the usual care for your breast cancer, your insurance will pay for these medications. You will be asked to complete forms which allow us to determine whether you are taking your medications as prescribed.

Who owns my study information and samples?
If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?
The exact side effects of radiation treatment given with palbociclib and hormone therapy is not known at this time.

If you choose to take part in this study, there is a risk that:

• You may lose time at work or home and spend more time in the hospital or study doctor's office than usual

• You may be asked sensitive or private questions which you normally do not discuss, although you may choose not to answer

The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

The most common risks and discomforts expected in this study are: fatigue, low white blood cell count, anemia, and sunburn type reaction from radiation which may occur in 30% or more of patients.

The less common risks and discomforts expected in this study are: nausea, diarrhea, hair loss which may occur in 10% to 30% of patients.

Rare but possible risks include: weakness, shortness of breath, cough, difficulty urinating, chest pain, abdominal pain, indigestion, dry mouth, fever, asthenia (general weakness), swelling of hands and feet, irritation or sores in the lining of hollow organs like mouth, throat, stomach, bowels; influenza (flu) like illness, pain in the muscles and bone including around the chest, muscle cramps, increases in blood liver markers that may indicate liver damage, dry skin, itching, mouth/throat pain, nosebleed, impaired sense of taste, high blood pressure, depression, bone fracture, and fall which may occur in up to 5 to 10% of patients .

The following side effects have been reported in <5% of patients on palbociclib, radiation, and hormone therapy, but are still deemed important: fever associated with dangerously low levels of a type of white blood cell (neutrophils), decreases in lymphocyte blood cells (infection fighting cells), blurred vision, increased tearing, nerve injury, paralysis, heart attack, death, and dry eye.

Here are important points about side effects:
The study doctors do not know who will or will not have side effects.
• There might be other side effects that researchers do not yet know about.
• Some side effects may go away soon, some may last a long time, or some may never go away.
• Some side effects may interfere with your ability to have children.
• Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:
• Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
• The study doctor may be able to treat some side effects.
• The study doctor may adjust the study drug dosages to try to reduce side effects.

For information on risks of anti-hormone therapy, please talk to your study doctor.

Ask the study doctor if you have questions about the signs or symptoms of any side effects that you read about in this consent form.

You should get medical help and contact the study doctor or study staff if you have any of these or any other side effects during the study.

It is possible that taking Palbociclib or anti-hormone therapy may change how your regular medications, vaccines, or supplements work. It is very important that you tell the study doctor about any medications, supplements, or vaccines before you take them during the study.

Please tell the study doctor or study staff right away if you have any side effects. Please tell them if you have any other problems with your health or the way you feel during the study, whether or not you think these problems are related to the study drug.

It is possible that you could have problems and side effects of Palbociclib or anti-hormone therapy that nobody knows about yet, which include your cancer getting worse or even death.

If you are a woman: to protect against possible side effects of the study drug, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control or abstinence for the duration of the study. If you think that you have

gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

If you are a man: the effect of the study drug on sperm is not known. To protect against possible side effects, if you are a man you should not get a sexual partner pregnant while taking the palbociclib, hormeone therapy and for 3 months after the last dose. You and the study doctor should agree on a method of birth control to or abstinence use throughout the study.

Radiation Risks

In addition to radiation therapy you may receive additional radiation from diagnostic procedures to evaluate your condition. The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. However, the additional risk of radiation-induced cancer from these diagnostic procedures is low compared to the risks from the radiation therapy.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

It is not possible to know at this time if radiation given with palbociclib and hormone therapy is better than radiation alone. This study will help researchers learn things that may help people in the future.

Will I be compensated for my time and effort?

You will not be offered compensation for being in this study.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. For example, you could:

- Receive standard radiation treatment without taking palbociclib and hormone therapy at the same time
- Receive chemotherapy, surgical treatment, or radioactive pharmaceuticals for your bone metastasis, if possible
- Take part in a different study, if one is available
- Choose not to be treated for cancer

The study doctor will discuss these with you. You do not have to be in this study to be treated for metastatic breast cancer.

Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

De-identified data from this study, including your de-identified genetic information, may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What research samples are collected and how will they be used?

Your blood and tissue samples contain DNA, which makes up the genes that serve as the "instruction book" for the cells in our bodies. Researchers are interested in the way genes affect how the body responds to drugs. Using DNA from your blood, researchers will study your entire genetic sequence, known as your genome. The genome sequence will be read and this information will be stored. Your genomic data will be used to find differences and similarities among people with regard to response to or side effects of palbociclib, anti-hormone therapy, and radiation. Your genomic data and health information will be studied along with information from other participants in this study, and it will be stored for future studies by this research team. The results of genetic tests are for research only. Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples. Because the research tests on your blood samples collected for this study are not used for regular medical care, the test results will not be put in your medical record. These samples will be sent to and stored at Emory University. If you do not want these samples to be taken for the research, you should not join the study.

Blood Samples: Blood samples specifically for research will be taken during the pre-radiation visit, and at 1 other time point during your participation (11-16 weeks after radiation completion). These samples are required in order for you to take part in this study because the research on the samples is an important part of the study. They will help us determine if there are markers in your blood that are linked to how you respond to palbociclib, anti-hormone therapy, and radiation.

How will the information about me be kept private in the biobank?
Your identity will be protected as required by law and according to the policies of the biobank. Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few examples of the steps they will take:
1) When your sample(s) is sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
2) The list that links the unique code to your name will be kept separate from your sample and health information and will not be available to the biobank.

Information that identifies you will not be given to anyone, unless required by law. Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included. If research results are published, your name and other personal information will not be used. Note that the FDA or the European Medicines Agency (EMA) or other regulatory agencies may have access to biobank records.

What are the possible risks associated with the biobank?
1) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
2) The information shared may include your DNA results. Because your DNA information is unique to you, there is a chance that someone could trace it back to you. The risk of this happening is small, but may be greater in the future.
3) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance

that someone will identify you is small, but the risk may change in the future as people come up with new ways of tracing information.
4) In some cases, this information could be used to make it harder for you to get or keep a job or insurance.

There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is small, but cannot promise that they will not occur.

What if I change my mind about the banked samples?
If you decide you no longer want your samples to be used, you can call the study doctor, at the number on the first page of this form. The study doctor will let the researchers know. Then, any sample that remains in the biobank will no longer be used and related health information will no longer be collected. Samples or related information that have already been given to or used by researchers will not be returned.

How is my Genetic Information Protected? What are the Risks?

The Genetic Information Nondiscrimination Act (GINA) is a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:
• Health insurance companies and group health plans may not request your genetic information that we get from this research.
• Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that GINA does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees.
In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions: life insurance policies, disability income policies, accidental death or dismemberment policies, medicare supplement policies, long-term care insurance policies, credit insurance policies, specified disease policies, hospital indemnity policies, blanket accident and sickness policies, franchise policies issued on an insurance policy written as a part of workers' compensation equivalent coverage, or other similar limited accident and sickness policies.

Privilege
In the State of Georgia, your genetic information has special legal protections called "privilege," which means that the information cannot be used as evidence in a court. By signing this form and allowing us to use and disclose your genetic information for the purposes described in this consent, you waive any privilege with regard to that genetic information, meaning that the information loses this legal protection.

Medical Record:
If you have been an Emory, Grady Health System, and/or Saint Joseph's Hospital patient before, then you already have an Emory, Grady Health System, and/or Saint Joseph's Hospital medical record. If you have never been an Emory, Grady Health System, and/or Saint Joseph's Hospital patient, you do not have one. An Emory, Grady Health System, and/or Saint Joseph's Hospital medical record will be made for you if an Emory, Grady Health System, and/or provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory, Grady Health System, and/or Saint Joseph's Hospital medical record you have now or any time during the study.

Emory, Grady Health System, and/or Saint Joseph's Hospital may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Grady Health System medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record.

Tests and procedures done at non-Emory, Grady Health System, and/or Saint Joseph's Hospital places may not become part of your Emory, Grady Health System, and/or Saint Joseph's Hospital medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you get ill or injured from being in the study, Emory, Grady Health System, or Saint Joseph's Hospital will help you get medical treatment. Emory, Grady Health System, Saint Joseph's Hospital and the study supporter have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory, Grady Health System, Saint Joseph's Hospital, or study supporter employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Torres at [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you have Medicare or Medicaid: the sponsor may need information about your identity and your study treatment to give to the government agencies that run these programs.

Costs

The study supporter will pay for certain items and services that you may receive if you take part in this study. For example, although often part of routine medical care, it is possible that blood draws including complete blood cell count with differential may not be paid for by insurance, and in these instances, the study sponsor will be pay for this procedure. Although imaging studies like MRI, PET/CT, Bone Scans, and CT scans are also done as part of routine medical care in patients with metastatic breast cancer, the study sponsor may pay for these tests if not paid for by insurance.

Palbociclib, hormone therapy, and radiation are part of regular medical care and will be paid for by insurance. If you have insurance, Emory will submit claims to your insurance for items and services that the sponsor does not cover.

You will have to pay for the items or services for which the study supporter does not pay. The study supporter will not pay for your regular medical care. If you have insurance, Emory, Grady Health System, and/or Saint Joseph's Hospital will submit claims to your insurance for items and services that the sponsor does not cover. Emory, Grady Health System, and/or Saint Joseph's Hospital will send in only those claims for items and services that it reasonably believes your insurance will pay and that the study supporter has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory, Grady Health System, Saint Joseph's Hospital, and the study supporter will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory, Grady Health System, and/or Saint Joseph's Hospital will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

Main Study

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory, Grady Health System, and/or Saint Joseph's Hospital may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups, including co-investigators, to help conduct the study or to provide oversight for the study.
- Pfizer Oncology is the supporter of the study. The supporter may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory, Grady Health System, and/or Saint Joseph's Hospital offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, Grady Research Oversight Committee, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research, and the IRB, research and healthcare compliance offices, and offices of clinical research at Maine Medical Center, Piedmont Healthcare, John B. Amos Cancer Center, Peyton Anderson cancer Center at Navicent Health, Nancy N. and J.C. Lewis Cancer & Research Pavilion at St. Joseph's/ Candler Hospital System, and Massachusetts General Hospital, Harvard University.
    - Other researchers and centers that are a part of this study (see above).
    - Government agencies that regulate the research including: Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Mylin A. Torres, MD (PI)
Director, Glenn Family Breast Center
Louise and Rand Glenn Family Chair in Breast Cancer Research
Winship Cancer Institute
Associate Professor
Rm. 1307-A
Department of Radiation Oncology
Emory University School of Medicine
1365 Clifton Road NE
[redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information
Contact Dr. Mylin Torres at [redacted]3:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted]:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study.. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____
Name of Subject

_____	_____	____:____ am / pm
Signature of Subject (18 or older and able to consent)	**Date**	**Time (please circle)**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____	_____	____:____ am / pm
Signature of Person Conducting Informed Consent Discussion	**Date**	**Time (please circle)**